

# Abstract

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5 A method for testing the allergenicity of a heterologous protein produced by a plant or animal that has been genetically modified to produce that protein is disclosed. The method includes the steps of: (a) sensitizing a newborn dog from an atopic dog colony with a first extract prepared from tissue of the genetically modified plant or animal and containing a mixture of plant or animal proteins and the heterologous protein, by injecting or feeding the extract into the newborn dog; (b) after a period sufficient to allow the dog to establish an immune response to the sensitizing extract, challenging the dog with the extract; (c) observing the degree of allergic response provoked; (d) if a detectable skin reaction is observed, comparing the degree of skin reaction observed with that observed by carrying out steps (a)-(c) above, but where the sensitizing step (a) or applying step (b) is carried out with a second plant or animal extract containing substantially the same proteins as the first extract but lacking the heterologous protein; and (e) if the degree of skin reaction at 10 (c) is greater than that observed by carrying out steps (a)-(c) in accordance with step (d), identifying the heterologous protein as a potential allergen in humans. Also disclosed is a dog for use in testing a biological substance for allergenicity in humans, and compositions useful in practicing the method.

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